

### **REMARKS**

Claims 1-14 were previously pending. Claims 1 and 8 have been amended to advance prosecution. Claims 4 and 11 have been canceled. As a result, claims 1-3, 5-10, and 12-14 are pending with claims 1 and 8 being independent claims. No new matter has been added.

### **Rejections Under 35 U.S.C. §102**

The Examiner maintained the rejection of claims 1-3, 6-10 and 13-14 under 35 U.S.C. §102(e) as anticipated by Mechanic, U.S. patent 5,332,475 ("Mechanic '475") and reiterated the same arguments made in the Office Action dated August 17, 2004. According to the Examiner, "Mechanic (col. 2, lines 42-68; col. 3, lines 1-2 col. 4, lines 19-53) discloses using collagen fibrils or finely ground bovine skin collagen in a cross-linking process not subjected to an acid dissolution to make collagen fiber/fabric/matrix to be used inside a human being as an implant. Inherently, the product to be used inside a human body must have been sterilized." The Examiner further stated that "Mechanic - '475 (col. 4, lines 38-64; claim 2 lines 1-8) clearly discloses a process comprising using a proteinaceous such as finely ground bovine skin collagen suspended in buffer media (which has a pH in a range of 6.8 to 8.6) such as water (pH about 7)" (emphasis added).

Applicant had previously amended independent claims 1 and 8 to overcome the 35 U.S.C. §102 rejection of the claims as being anticipated by Mechanic '475. In particular, Applicant amended claims 1 and 8 by adding the limitation "wherein the collagen fibrils have been suspended in water" to distinguish over Mechanic '475. Based on the teachings of the Mechanic '475, its parent patent (U.S. patent 5,147,514 ("Mechanic '514")), a review of the file history of both patents, and evidence in the scientific literature, Applicant previously argued that the above amendment would distinguish over Mechanic.

Applicant argued that because water is not a buffer and because Mechanic '475 does not teach using non-buffered water or non-buffered aqueous media to suspend collagen, the above-recited amendments to claims 1 and 8 should overcome the §102 rejection. For the sake of brevity, the Examiner is referred to the prior responses submitted by the Applicant on May 17,

2004, February 17, 2005, and May 26, 2005 for further elaboration on Applicant's above-presented argument and reasoning.

Applicant's prior responses and the submitted supporting documentation, including scientific literature evidence, were considered by the Examiner but were not found to be persuasive. The Examiner disagreed with the Applicant's arguments, reasoning, and position that water is not a buffer medium despite the presented scientific literature evidence attesting to the fact that water is not a buffer and has no buffering capacity. The Examiner argued that Mechanic discloses proteinaceous material being suspended in aqueous media such as water (having pH of from about 6.8 to 8.6) and that "water having a pH about 7 (neutral) which is well within the pH range of 6.8 – 8.6 disclosed by Mechanic –'475, must be considered as a buffer medium" (emphasis added). The examiner asserted that there is no language or feature to distinguish the present invention over Mechanic '475.

Without conceding the correctness of the Examiner's position and to advance prosecution, Applicant has amended independent claims 1 and 8. Claims 1 and 8 have been amended to introduce the limitations of claims 4 and 11 respectively, namely "wherein the collagen fibrils have a bulk density in the range of from about 1.5 to about 3.5 lbs/ft<sup>3</sup>." Applicant reserves the right to pursue claims of scope similar to claims 1 and 8 before the currently introduced amendments.

Mechanic '475 does not teach collagen fibrils having a bulk density in the range of from about 1.5 to about 3.5 lbs/ft<sup>3</sup>. Accordingly, Mechanic '475 does not anticipate the claims as currently amended. In view of the above amendments and foregoing statements, Applicant respectfully requests that the Examiner reconsider and withdraw the §102 rejection of claims 1-3, 6-10, and 13-14.

### **Rejections Under 35 U.S.C. §103**

The Examiner maintained the rejection of claims 4-5 and 11-12 under 35 U.S.C. §103(a) as being unpatentable over Mechanic '475. As to claims 4 and 11, the Examiner asserts that Mechanic discloses a cross-linked collagen product having substantially all the limitations in the

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claims except for a bulk density from 1.5 to about 3.5 lbs/ft<sup>3</sup>. According to the Examiner, Mechanic discloses that one can select a collagen source according to one's intended use of the cross-linked collagen product and that "[i]t would have been obvious to one of ordinary skill in the art to select a specific range of density such as the range claimed to fit one's need/application."

As to claims 5 and 12, the Examiner asserts that Mechanic discloses a cross-linked collagen product having substantially all the limitations in the claims except for a hemostatic agent. According to the Examiner, "[i]t is well known to incorporate a hemostatic agent to a collagen product such a fabric/matrix/pad to enhance hemostatic effect" and that "[i]t would have been obvious to one of ordinary skill in the art to incorporate a hemostatic agent to the MECHANIC collagen product so as to enhance the hemostatic effect of the MECHANIC collagen product."

Applicant respectfully traverses the rejection for at least the following reasons. The Examiner has not made a *prima facie* case for rejecting the claims under §103. A *prima facie* case of obviousness requires some suggestion or motivation to modify the teaching of the reference and a have a reasonable expectation of success in doing so. Regardless of whether one of ordinary skill in the art could have modified an art reference, the requirement for making an obviousness rejection is that the person of ordinary skill in the art have some motivation to make the substitution. The suggestion or motivation to modify the teaching may be found either in the reference itself or in the knowledge generally available to one of ordinary skill in the art (MPEP § 2143). Describing "the teaching or the motivation to combine is an essential evidentiary component of an obviousness holding." *C. R. Bard Inc. v M3 Sys. Inc.* 157 F.3d 1340, 1352 (Fed. Cir. 1998).

The Examiner has not made out a *prima facie* case of obviousness, because the Examiner has not provided the motivation for one of ordinary skill in the art to modify Mechanic '475 in the manner suggested by the Examiner. Mechanic '475 does not teach or suggest the claim limitation of claims 4 and 11, namely "a bulk density in the range of from about 1.5 to about 3.5 lbs/ft<sup>3</sup>" nor the claim limitation of claims 5 and 12, namely "hemostatic agent." The Examiner

has not provided any description or supporting evidence of the motivation that the skilled person would have had in making the modifications to Mechanic '475 as suggested by the Examiner.

As stated in MPEP § 2144.03, facts that are purportedly common knowledge or "well-known" should only be relied upon to "fill the gaps" in the prior art and should not comprise the principle evidence upon which a rejection is based. Here, the Examiner's entire basis for modifying Mechanic '475 is without support in the prior art of record, which is respectfully believed to render the rejection improper under MPEP § 2144.03.

If the assertion that it would have been obvious to modify Mechanic '475 in the manner suggested by the Examiner is to be maintained, the Examiner is respectfully requested to cite a reference in support of this position, as required under MPEP § 2144.03. Alternatively, if facts within the Examiner's personal knowledge are being relied upon, the Examiner is respectfully requested to file an affidavit establishing those facts pursuant to MPEP § 2144.03.

Even assuming, for arguments sake, that the teachings of Mechanic '475 provide the motivation for one skilled in the art to modify the reference, which the Applicant disagrees with for the reasons discussed above, the required reasonable expectation of success is absent because Mechanic '475 does not provide guidance as to making the claimed invention. Thus, without any specific guidance in Mechanic '475, there would be no reasonable expectation that one of ordinary skill in the art would have succeeded in arriving at the claimed invention.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 4-5 and 11-12 under 35 U.S.C. 103.

### **CONCLUSION**

In view of the foregoing remarks, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims under 35 U.S.C. 102 and under 35 U.S.C. 103. This application should now be in condition for allowance. A notice to this effect is respectfully requested.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time.

If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

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